IUCLID

Data Set

Existing Chemical

CAS No.

EINECS Name

EC No.

Molecular Formula

: ID: 2426-08-6

2426-08-6

butyl 2,3-epoxypropyl ether

: 219-376-4

: C7H14O2

Producer related part

Company Creation date : Huntsman (Europe) BVBA (ehemals ICI Polyurethanes)

: 07.06.2006

Substance related part

Company Creation date Huntsman (Europe) BVBA (ehemals ICI Polyurethanes)

: 07.06.2006

Status

Memo

: SPI HPV chemical

Printing date

Revision date

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Chapter (profile)

Reliability (profile)

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Flags (profile)

Reliability: without reliability, 1, 2, 3, 4 Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE). Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1. General Information

ld 2426-08-6 Date 19.06.2006

1.0.1 APPLICANT AND COMPANY INFORMATION

Type

other: lead organization

Name

Epoxy Resin Systems Task Group of The Society of the Plastics Industry,

Inc..

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07.06.2006

1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

1.0.3 IDENTITY OF RECIPIENTS

1.0.4 DETAILS ON CATEGORY/TEMPLATE

1.1.0 SUBSTANCE IDENTIFICATION

1.1.1 GENERAL SUBSTANCE INFORMATION

1.1.2 SPECTRA . . .

1.2 -SYNONYMS AND TRADENAMES

IMPURITIES

1.5 TOTAL QUANTITY

1.6.1 LABELLING

Date 19.06.2006 1.6.2 CLASSIFICATION 1.6.3 PACKAGING 1.7 USE PATTERN 1.7.1 DETAILED USE PATTERN 1.7.2 METHODS OF MANUFACTURE 1.8 REGULATORY MEASURES 1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES 1.8.2 ACCEPTABLE RESIDUES LEVELS 1.8.3 WATER POLLUTION 1.8.4 MAJOR ACCIDENT HAZARDS 1.8.5 AIR POLLUTION 1.8.6 LISTINGS E.G. CHEMICAL INVENTORIES 1.9.1 DEGRADATION/TRANSFORMATION PRODUCTS 1.9.2 COMPONENTS 1.10 SOURCE OF EXPOSURE 1.11 ADDITIONAL REMARKS 1.12 LAST LITERATURE SEARCH 1.13 REVIEWS

Id 2426-08-6

1. General Information

2. Physico-Chemical Data

ld 2426-08-6 Date 19.06.2006

2.1 MELTING POINT
2.2 BOILING POINT
2.3 DENSITY
2.3.1 GRANULOMETRY
2.4 VAPOUR PRESSURE
2.5 PARTITION COEFFICIENT
2.6.1 SOLUBILITY IN DIFFERENT MEDIA
2.6.2 SURFACE TENSION
2.7 FLASH POINT
2.8 AUTO FLAMMABILITY
2.9 FLAMMABILITY
2.10 EXPLOSIVE PROPERTIES
2.11 OXIDIZING PROPERTIES
2.12 DISSOCIATION CONSTANT
2.13 VISCOSITY
2.14 ADDITIONAL REMARKS

3. Environmental Fate and Pathways

ld 2426-08-6 **Date** 19.06.2006

3.1.1 PHOTODEGRADATION

3.1.2 STABILITY IN WATER

Type

: abiotic

t1/2 pH4

ca. 0.3 hour(s) at 20 °C

t1/2 pH7

486.7 hour(s) at 20 °C

t1/2 pH9 t1/2 pH 4

: ca. 1 hour(s) at 10 °C

Deg. product

no

Method

: OECD Guide-line 111 "Hydrolysis as a Function of pH"

Year GLP :

Test substance

other TS: Butyl glycidyl ether, CAS 2426-08-6, Purity: 99.8%

Method

: A preliminary experiment was used to determine the approximate rate of hydrolysis of the test substance and the course of further testing. This test was performed at all three pH levels (4.0, 7.0 and 9.0) at 50 ± 0.1°C for five days and the outcomes determined further testing.

A sample of test substance was weighed into an autoclaved vial of sterile buffer solution (pH 4.0, 7.0 and 9.0) and then dispersed by syringe to appropriately labeled, autoclaved containers using aseptic technique. The containers were sealed, covered with foil, purged with nitrogen and placed in the appropriate constant temperature bath until retrieved for sampling. The quantity of containers was sufficient to allow for removal of one

container at each time point.

Aliquots of solution from each test vessel were extracted and analyzed by high performance liquid chromatography (HPLC)using a Varian Prostar HPLC with Model 320 UV-VIS detector at a wavelength of 210 nm. The standard curve for the analysis was prepared from the unused test substance. Time points for the preliminary test were time zero and Day 5. Times for the definitive tests were chosen so that at least six time points were sampled at 20-70% of total hydrolysis. The half-life was determined assuming first order kinetics.

The rate of hydrolysis was extrapolated to 25° C for pH 4.0 and 7.0 using the Arrhenius equation: k(obs) = Ae-(Ea/RT) or In k(obs) = Ln A - Ea/RT

Result

: The rate of hydrolysis was determined to be:

19.64 1/s x 10e5 for pH 4.0 (10°C), 68.75 1/s x 10e5 for pH 4.0 (20°C), 0.04 1/s x 10e5 for pH 7.0 (20°C) 0.26 1/s x 10e5 for pH 7.0 (40°C)

There was not a determined rate of hydrolysis for pH 9.0 (50°C) since

hydrolysis was less than 10%. The extrapolated rates of hydrolysis for: 12.44 1s x 10e5 for pH 4.0 (25°C)

6.26 1/s x 10e5 for pH 7.0 (25°C)

Therefore, the test substance, n-Butyl glycidyl ether, CAS RN 2426-08-6, underwent rapid hydrolysis at pH 4.0. The rate of hydrolysis slowed down

as the pH was increased.

Reliability

(1) valid without restrictionGLP guideline study

Flag

: Critical study for SIDS endpoint

07.06.2006

(1)

3. Environmental Fate and Pathways ld 2426-08-6 Date 19.06.2006 3.1.3 STABILITY IN SOIL 3.2.1 MONITORING DATA 3.2.2 FIELD STUDIES 3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS 3.3.2 DISTRIBUTION 3.4 MODE OF DEGRADATION IN ACTUAL USE 3.5 BIODEGRADATION 3.6 BOD5, COD OR BOD5/COD RATIO 3.7 BIOACCUMULATION 3.8 ADDITIONAL REMARKS

4. Ecotoxicity	ld 2426-08-6 Date 19.06.2006
4.1 ACUTE/PROLONGED TOXICITY TO FISH	
4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRA	TES
4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE	
4.4 TOXICITY TO MICROORGANISMS E.G. BACTE	FRIA
4.5.1 CHRONIC TOXICITY TO FISH	
4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBR	ATES
4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANIS	SMS
4.6.2 TOXICITY TO TERRESTRIAL PLANTS	
4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS	
4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES	
47 PIOLOGICAL EFFECTS MONITODING	

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5. Toxicity ld 2426-08-6 Date 19.06.2006

- 5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION
- 5.1.1 ACUTE ORAL TOXICITY
- 5.1.2 ACUTE INHALATION TOXICITY
- 5.1.3 ACUTE DERMAL TOXICITY
- 5.1.4 ACUTE TOXICITY, OTHER ROUTES
- 5.2.1 SKIN IRRITATION
- 5.2.2 EYE IRRITATION
- 5.3 SENSITIZATION
- 5.4 REPEATED DOSE TOXICITY
- 5.5 GENETIC TOXICITY 'IN VITRO'

Type

System of testing

Chromosomal aberration test Chinese Hamster Ovary cells

Test concentration

37.5 to $500~\mu g/mL$ for the 4 hour groups and 18.75 to $350~\mu g/mL$ for the 20

Cycotoxic concentr.

400 µg/mL for the 4 hour non-activated group, 200 µg/mL for the 20 hour non-activated group, and 350 µg/mL for the S-9 activated group.

Metabolic activation

Result

with and without

Method Year

OECD Guide-line 473

GLP

1998 yes

Test substance

other TS: Butyl glycidyl ether, CAS 2426-08-6, Purity: 99.8%

Method

: Acetone was determined to be the solvent of choice. The test article was soluble in acetone and in the treatment medium at all dose levels tested. Aroclor 1254-induced rat liver S9 was used as the metabolic activation system. The cells were treated for 4 and 20 hours in the non-activated test system and for 4 hours in the S9-activated test system. All cells were harvested 20 hours after treatment initiation.

The study was conducted in compliance with the testing guidelines of the ICH (1996 and 1997) and OECD (1998).

Result

The percentage of cells with structural aberrations in the non-activated 4hour exposure group was significantly increased (6.0% and 18.0%, respectively) above that of the solvent control at dose levels 350 and 400 μg/mL (p<0.01, Fisher's exact test). The Cochran-Armitage test was also

5. Toxicity

id 2426-08-6 Date 19.06.2006

positive for a dose response (p<0.05). The percentage of cells with numerical aberrations in the test article-treated group was not significantly increased above that of the solvent control at any dose level (p>0.05, Fisher's exact test).

The percentage of cells with structural aberrations in the S9-activated 4hour exposure group was significantly increased (7.0% and 10.5%, respectively) above that of the solvent control at dose levels 300 and 350 μg/mL (p<0.01, Fisher's exact test). The Cochran-Armitage test was also positive for a dose response (p<0.05). The percentage of cells with numerical aberrations in the test article-treated group was not significantly increased above that of the solvent control at any dose level (p>0.05, Fisher's exact test).

The percentage of cells with structural aberrations in the non-activated 20hour exposure group was significantly increased above that of the solvent control at dose levels 37.5 and 200 µg/mL (p<0.05, Fisher's exact test). The Cochran-Armitage test was negative for a dose response (p>0.05). However, the percentage of cells with structural aberrations in the test article-treated group (3.0% at both dose levels) was within the historical solvent control range of 0.0% to 5.0%. Therefore, it is not considered to be biologically significant. The percentage of cells with numerical aberrations in the test article-treated group was not significantly increased above that of the solvent control at any dose level (p>0.05, Fisher's exact test).

Conclusion

Under the conditions of the assay described in this report, n-Butyl glycidyl ether was concluded to be positive for the induction of structural chromosome aberrations and negative for the induction of numerical chromosome aberrations in CHO cells.

Reliability

(1) valid without restriction GLP quideline study

Flag

Critical study for SIDS endpoint

07.06.2006

(2)

5.6 GENETIC TOXICITY 'IN VIVO'

5.7 CARCINOGENICITY

5.8.1 TOXICITY TO FERTILITY

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Species

rat

Sex

female Crj: CD(SD)

Strain

gavage

Route of admin.

Exposure period

Gestation days 0 through 19

Frequency of treatm. **Duration of test**

once daily

Doses

Through gestation day 20. 40, 100 and 250 mg/kg/day administered at a dosage volume of 5 mL/kg.

Control group

yes, concurrent vehicle

NOAEL maternal tox. NOAEL teratogen.

250 ml/kg bw

100 ml/kg bw

Result

Developmental effects were seen at the highest dose tested. No maternal

toxicity was observed.

Method Year

OECD Guide-line 414 "Teratogenicity"

GLP

yes

5. Toxicity

ld 2426-08-6 **Date** 19.06.2006

(3)

Test substance

: other TS: Butyl glycidyl ether, CAS 2426-08-6, Purity: 99.8%

Method

The test article, N-butyl glycidyl ether, in the vehicle, 0.5% methylcellulose (MC) with 0.1% polysorbate 80, was administered orally by gavage to 3 groups of 25 bred female Crl:CD®(SD) rats once daily from gestation days 0 through 19. Dosage levels were 40, 100 and 250 mg/kg/day administered at a dosage volume of 5 mL/kg. A concurrent control group composed of 25 bred females received the vehicle on a comparable regimen. All animals were observed twice daily for mortality and moribundity. Clinical observations, body weights and food consumption were recorded at appropriate intervals. On gestation day 20, a laparohysterectomy was performed on each female. The uteri, placentae and ovaries were examined, and the numbers of fetuses, early and late resorptions, total implantations and corpora lutea were recorded. Gravid uterine weights were recorded, and net body weights and net body weight changes were calculated. The fetuses were weighed, sexed and examined for external, visceral and skeletal malformations and developmental variations.

Result

: All animals in the control, 40, 100 and 250 mg/kg/day groups survived to the scheduled necropsy. Test article-related, but not adverse, salivation immediately prior to and/or 1 hour following dose administration was noted for animals in the 250 mg/kg/day group.

Mean maternal body weights, body weight gains, net body weights, net body weight gains and food consumption in the all groups were unaffected by test article administration.

Intrauterine growth and survival were unaffected by test article administration at dosage levels of 40 and 100 mg/kg/day.

Increased postimplantation loss with corresponding decreased litter viability was observed at the 250 mg/kg/day dosage level. This, in conjunction with decreased fetal weight (primarily due to 7 litters with mean fetal weights less than 2.2 g), resulted in lower mean gravid uterine weight at this dosage level

Developmental delay was also evident at the 250 mg/kg/day dosage level by skeletal developmental variations of unossified and reduced ossification of skeletal elements an unco-ossified vertebral centra in the litters with low fetal weights.

Therefore, the no-observed-adverse-effect level (NOAEL) for embryo/fetal

development was considered to be 100 mg/kg/day.

No maternal toxicity was noted at any dosage level in this study. Therefore, the NOAEL for maternal toxicity was considered to be 250 mg/kg/day.

Reliability

: (1) valid without restriction

GLP guideline study

Flag 07.06.2006 : Critical study for SIDS endpoint

5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

5.9 SPECIFIC INVESTIGATIONS

5.10 EXPOSURE EXPERIENCE

5.11 ADDITIONAL REMARKS

6. Analyt. Meth. for Detection and Identification

ld 2426-08-6 Date 19.06.2006

6.1 ANALYTICAL METHODS

6.2 DETECTION AND IDENTIFICATION

7. Eff. Against Target C	Org. and Int	ended	Uses	Da		2426-08-6 19.06.2006
7.1 FUNCTION						
7.2 EFFECTS ON ORGANIS	MS TO BE CON	TROLLED				
7.3 ORGANISMS TO BE PRO	OTEGTED					
The state of the s						
7.4 USER						
7.5 RESISTANCE						
					•	

8. Meas. Nec. to Prot. Man, Animals, Environment

ld 2426-08-6 **Date** 19.06.2006

- 8.1 METHODS HANDLING AND STORING
- 8.2 FIRE GUIDANCE
- 8.3 EMERGENCY MEASURES
- 8.4 POSSIB. OF RENDERING SUBST. HARMLESS
- 8.5 WASTE MANAGEMENT
- 8.6 SIDE-EFFECTS DETECTION
- 8.7 SUBSTANCE REGISTERED AS DANGEROUS FOR GROUND WATER
- 8.8 REACTIVITY TOWARDS CONTAINER MATERIAL

9. References Id 2426-08-6 Date 19.06.2006

- (1) Stillmeadow, Inc. Sugar Land, Texas. Study no. 9080-05. January, 2006
- (2) BioReliance, Rockville, Maryland. Study Number AB10UF.331.BTL. September, 2005
- (3) WIL Research Laboratories, LLC. Ashland, OH. Study No. WIL-284003. May, 2006

10. Summary and Evaluation

ld 2426-08-6 **Date** 19.06.2006

10.1 END POINT SUMMARY

10.2 HAZARD SUMMARY

10.3 RISK ASSESSMENT